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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,471	02/27/2007	Tatsuya Konishi	KPO-TSC-P3/TK-93/US	3141

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
06/02/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,471	KONISHI ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/29/10*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicant's amendments filed on November 29, 2011 are acknowledged and have been considered. **Claims 11, 13, and 15-20 are pending.** **Claims 11, 13, and 15-20 are under examination in the instant office action**. Claims 1-10, 12, and 14 are cancelled. Claim 20 is newly added.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. § 102(b) as being anticipated by Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) as evidenced by Patel et al. (US Patent No. 4855294), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicant argues a counter- irritant is not the same thing as an anti-irritant. "A counterirritant is a substance which creates inflammation in one location with the goal of lessening the inflammation in another location. In contrast, an anti-irritant is defined as "substances that sooth the localized/superficial inflammation of the skin that is due directly to one or more external substances.". The Patel et al., reference, USP 4,855,294, uses glycerin to reduce the skin irritation properties of a transdermal drug/permeation enhancer composition. See col. 2, lines 23-28 of the enclosed Patel reference. A compound that reduces irritation can be called an anti-irritant. As noted in the enclosed article (N. Atrux-Tallau et al.), which describe glycerin (glycerol) as a humectant. As a humectant, glycerin is not acting a

counter-irritant. Glycerin does not cause a slight inflammation. As defined in the application, "[i]ngredients having a counter-irritation effect, so-called counter-irritants, are agents that cause a slight inflammation upon a topical application to the skin and thereby dissipate the congestion in the tissue below. Counter-irritants are used to alleviate the congestion in the deep tissue by taking advantage of their ability to stimulate the skin and cause a slight inflammation.

These assertions are not found persuasive because indeed glycerin is a counterirritant contrary to applicant's assertions. In order to rebut applicant's assertions the examiner substantiates his position by incorporating McPeak et al., (US Patent No. 6902739) , in response to applicant's arguments to shoe that glycerin (glycerol) is indeed a counterirritant. McPeak et al., teach methods and formulations for treating an inflammatory disease or reducing an inflammatory reaction comprising administering a fortified formulation comprising stabilized rice bran derivative and a fortification agent. Preferred rice bran derivatives are rice bran oil and the solubilized fraction of rice bran. Preferred fortification agents are glucosamine derivative, methylsulfonylmethane, yucca concentrate, and grape seed extract (see abstract). McPeak et al., teach that in pharmaceutical dosage forms, the present methods can use formulations where compounds are administered in the form of their pharmaceutically acceptable salts, or they may also be used alone or in appropriate association, as well as in combination with other pharmaceutically active compounds (column 16, lines 47-53). Agents of particular use in the formulations of the present invention include, for example, local anesthetics, **counterirritants**, anti-inflammatory agents, or any agent that has a therapeutic effect for inflammatory diseases or conditions (column 16, lines 53-57). **The preferred counterirritants include, but are not limited to, glycerol**, corticosteroids and salicylates (column 16, lines 66-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 11, 13, and 16-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) in view of Hirashima et al. (US Patent No. 6471984) and as evidenced by Patel et al. (US Patent No. 4855294), for the reasons of record and the reasons set forth herein.

Additionally, <u>newly added claim 20</u> is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent

No. 7018647), further in view of Bernstein (US Patent No. 4997853), and as evidenced by Patel et al. (US Patent No. 4855294) as well.

Response to arguments

Applicant argues that there is no reason, other than hindsight using the present application, to select benzocaine out of this list. As stated in the Hirashima reference: The drug to be used in the patch of this invention is not particularly limited but may be arbitrarily selected from among known conventional drugs. Even more telling, methyl salicylate and glycol salicylate are buried in a list of dozens of additives to the hydrophilic base of Hirashima and identified as ultraviolet absorbers or anti-inflammatory agents, not as counter-irritants. As identified as in Hirashima, one skilled in the art would not use these compounds as counter-irritants. No one skilled in the art would have any reason to combine these two random components of the Hirashima et al. patent except by using the present application as a guide and impermissible hindsight to conduct a computer search to select these two items out of the hundreds listed in the Hirashima et al. reference. Moreover, Hirashima does not list the other counter-irritants claimed.

These assertions are not found persuasive because contrary to applicant's attention Hirashima's patch is capable of delivering the conventionally known drugs with no limitation. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Whether Hirashima calls methyl salicylate and glycol salicylate atan ultraviolet absorber or anti-inflammatory agent does not really matter. The counter-irritation effect of methyl saliciylate and glycol salicylate is inseparable from the compounds. It is an innate chemical property of the compounds. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Yamasaki et al. by incorporating the

counter-irritation agent recited in instant claims 13 and 16 in the medical adhesive patch, because Hirashima et al. teaches that counter-irritants like **glycol salicylate, methyl salicylate and phenyl salicylate** can be included in a patch that may contain drugs like benzocaine to alleviate pain and skin irritation. An ordinary skilled artisan would have been motivated to substitute the counter-irritant glycerin with the other counter-irritants recited in instant claims 11, 13, and 16-17 because the anti-irritation agents are functionally equivalent and can equally perform the intended purpose. Furthermore, the ingredients with the counter irritation effect are conventionally known in the art. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of the Yamasaki et al. and Hirashima et al., because both references teach similar compositions delivered in a patch for alleviation of pain. Furthermore, The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant further argues that Patel et al. is incorporated in the rejection as an evidential reference in order to verify that glycerin is an anti-irritation agent. Claim 1 of Patel et al. calls for "an effective amount of glycerin to reduce the irritation of said drug-enhancing composition." The abstract of the Patel et al. reference calls "for reducing the skin irritation properties of a transdermal drug/enhancer composition." As noted above, Patel teaches an anti- irritant, a humectant, a soothing compound, glycerin, not a counter-irritant as disclosed and claimed in the present application. Glycerin reduces irritation; it does not cause inflammation, as required for a counter-irritant.

These assertions are not found persuasive because indeed glycerin is a counterirritant contrary to applicant's assertions. In order to rebut applicant's assertions the examiner substantiates his position by incorporating McPeak et al., (US Patent No. 6902739) to prove that glycerin (glycerol) is indeed a counterirritant. McPeak et al., teach methods and formulations for treating an inflammatory disease or reducing an inflammatory reaction comprising administering a fortified formulation comprising stabilized rice bran derivative and a fortification agent. Preferred rice bran derivatives are rice bran oil and the solubilized fraction of rice bran. Preferred fortification agents are glucosamine derivative, methylsulfonylmethane, yucca concentrate, and grape seed extract (see abstract). McPeak et al., teach that in pharmaceutical dosage forms, the present methods can use formulations where compounds are administered in the form of their pharmaceutically acceptable salts, or they may also be used alone or in appropriate association, as well as in combination with other pharmaceutically active compounds (column 16, lines 47-53). Agents of particular use in the formulations of the present invention include, for example, local anesthetics, **counterirritants**, anti-inflammatory agents, or any agent that has a therapeutic effect for inflammatory diseases or conditions (column 16, lines 53-57). **The preferred counterirritants include, but are not limited to, glycerol**, corticosteroids and salicylates (column 16, lines 66-67).

Claims 11, 13, and 16-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) and further in view of Bernstein (US Patent No. 4997853) and as evidenced by Patel et al. (US Patent No. 4855294) for the reasons of record and the reasons set forth herein. Additionally, newly added claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647), further in view of Bernstein (US Patent No. 4997853), and as evidenced by Patel et al. (US Patent No. 4855294) as well.

Response to arguments

Applicant argues that Yamasaki et al and Patel have already been discussed in depth. Bernstein only discloses capsaicin; there is no mention or suggestion of 1-menthol, dl-menthol, dl- camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil, eucalyptus oil, or and nonylic vanillylamide, nor the suggestion of using up to 20 wt% of capsaicin. The largest amount of capsaicin suggested in Bernstein is 1 wt% (see claim 5 and column 1, line 42 of the Bernstein reference). In particular, new claim 20 claims a range of at least 5% benzocaine up to 15%. In addition, the focus of the Bernstein reference is to use benzocaine to reduce burning and pain caused by use of capsaicin. There is nothing in Bernstein that would suggest the combination of benzocaine and counter-irritant for non-superficial pain, since Bernstein is directed to "superficial pain syndromes such as postherpetic neuralgia" (See column 1, lines 13-14). The present application is directed to deep muscle, joint and bone pain as noted in paragraph [0001] of the application as filed and claimed in claims 11, 16 and 20.

These assertions are not found persuasive because the Markush recitation is in the alternative. For Bernstein to be combinable with the other reference Bernstein does not have to teach all of the counter-irritation agents. The fact that Bernstein teaches capsaicin is good enough to render the claims obvious. Applicant's claimed limitation only requires 0.01 to 5% capsaicin not up to 20%. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., up to 20% capsaicin) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Bernstein teaches a method for treating superficial pain syndromes, said method comprising the step of topically applying to a patient having superficial pain, an effective amount of a composition comprising a therapeutically acceptable carrier and capsaicin, said **capsaicin being present in a concentration, by weight, from about 0.01% to about 1.0%**, said composition also including a topical

anesthetic in a therapeutically effective amount, said anesthetic being present primarily to inhibit the local topical irritant effect of said capsaicin and whereby said capsaicin provides the primary relief for the pain syndrome (see claim 1). The anesthetic can be **benzocaine** (see claim 3). Regarding the amount of benzocaine recited in the newly added claim 20 Yamasaki et al., which is the primary reference clearly disclose **an external skin patch comprising a formulation of benzocaine (7% w/w), based on examiner's calculation 48.3 % of water, glycerin (counter-irritant) (10%) and other ingredients** (column 6, example 2, and lines 28-54) which renders the claim obvious.

Applicant also argues that in addition, the focus of the Bernstein reference is to use benzocaine to reduce burning and pain caused by use of capsaicin. There is nothing in Bernstein that would suggest the combination of benzocaine and counter-irritant for non-superficial pain, since Bernstein is directed to "superficial pain syndromes such as postherpetic neuralgia" (See column 1, lines 13-14). The present application is directed to deep muscle, joint and bone pain as noted in paragraph [0001] of the application as filed and claimed in claims 11, 16 and 20.

These assertions are not found persuasive because so long as the structure contains benzocaine and counter-irritation agent such as capsaicin the prior art product is capable of meeting the intended use applicant asserts. The examiner takes the position that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The examiner notes that indeed the prior art structure is capable of performing the intended use since structurally it is similar to the instantly claimed product.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on 571-272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 5/23/11

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647